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10/521,126	07/10/2006	Catharina Everdina Hissink	294-207 PC'D/US	6484
23869 7590 02/26/2010 HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791				
EXAMINER				
PALENIK, JEFFREY T				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/521,126

Applicant(s)

HISSINK, CATHARINA EVERDINA

Examiner

Jeffrey T. Palenik

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-17, 27 and 31-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-17, 27 and 31-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

STATUS OF THE APPLICATION

Receipt is acknowledged of Applicant's Request for Continued Examination (RCE), Amendments, Remarks and Declaration filed 31 August 2009. Said documents are entered on the record. The Examiner further acknowledges the following:

No claims have been added or cancelled.

Claim 11 has been amended to such that it now depends from claim 9 rather than claim 10.

No new matter has been added.

As such, claims 1, 3-17, 27 and 31-37 continue represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statement (IDS) have been submitted for consideration.

WITHDRAWN OBJECTIONS/REJECTIONS

Rejection under 35 USC 103

Applicants' Declaration submitted under 37 CFR 1.132 has been considered in parallel with the remaining remarks. Both argue that the Penco reference fails to teach or suggest that the segments of the copolymer are extended using an independent aliphatic chain extender as instantly claimed (e.g. PEG). The grounds for the traversal have been reconsidered by the Examiner and are **persuasive**. As such the rejection to claims 1, 3-17 and 27 under 35 USC 103 as being unpatentable over the combined teachings of Penco in view of Cohn '662 is **withdrawn**.

MAINTAINED REJECTION

The following rejection is maintained from the Final Office Action dated 31 March 2009:

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 4, 9, 13, 14 and 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohn et al. (US Pre-Grant Publication 2001/0009662).

The instantly amended claim 1 is drawn to a multiblock copolymer comprising pre-polymer (A) and pre-polymer (B), wherein (A) and (B) are linked by an aliphatic chain extender and wherein the segments are randomly distributed within the copolymer. Amended claim 3 further limits claim 1 such that pre-polymer (A) comprises ester and/or carbonate groups. Claim 31 further limits claim 3, such that the composition further comprises polyethers. Claims 4, 9, 32 and 33 further limit the composition of claim 1 such that it further comprises polyethylene glycol (PEG) having a molecular

weight between 300-1,000 (e.g. PEG400). Claims 13 and 14 further limit the pre-polymer (B) of claim 1, to poly-ε-caprolactone. Claims 34 and 35 further limit claim 14 such that pre-polymer (B) has an average molecular weight of greater than 2,000 and 3,000, respectively (e.g. PCL 4,000). Claim 36 recites that pre-polymer (B) is present between 30-50 wt% of the composition. With regard to the intrinsic viscosity limitation recited in claim 37, which states that the composition of claim 1 has "an intrinsic viscosity of between 1-4 dL/g"; until some material difference in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the composition, which is instantly claimed.

Cohn et al. expressly teaches the limitations of claims 1, 3, 4, 9 and 31 at ¶[0092] and [0012], such that a composition is administered which comprises ACA triblock copolymers which are chain-extended and comprise polyethylene oxide ¶[0092]. Paragraph [0012] further teaches that block "A" of the triblock is a polyester which is preferably derived from the polymerization of monomers such as lactide, glycolide, ε-caprolactone, δ-valerolactone, trimethylene carbonate, 1,4-dioxane-2-one and p-dioxanone (e.g. cyclic monomers), lactic, glycolic and/or hydroxybutyric acids (e.g. non-cyclic monomers), as well as mixtures thereof. Paragraph [0092] further teaches that block "A" also preferably comprises aliphatic ester units. The teaching of ε-caprolactone, δ-valerolactone and p-dioxanone are expressly taught examples of both pre-polymers (A) and (B) of claims 6-8 and 13-14. Regarding the limitations of the instant claims 32 and 33, the polyether compound polyethylene glycol (PEG) is expressly taught as a preferred embodiment of block "C" of the triblock copolymer and is even more preferably taught as ranging in size from 400 to 10,000 Daltons ¶[0102]. The limitations of pre-polymer (B) set forth in claims 34-36 are taught by Example 10, which teaches the formation of a copolymer composition using a caprolactone

polyester compound having a molecular weight of 4,000. Also, in Example 10, it is taught that PCL 4000 represents 20 grams of a 66 gram formulation (e.g. about 30%).

It would have been *prime facie* obvious to a person of ordinary skill in the art at the time the invention was made to have prepared the instantly claimed multiblock copolymer, particularly in view of the teachings of Cohn et al. Given the following notable and aforementioned properties of block "A" of the ACA triblock copolymer:

- that it is a polyester which may be formed from a large selection of different monomer building blocks which read on the compounds of both of the instantly claimed pre-polymers (A) and (B), and that
- it preferably comprises aliphatic chain extensions,

it follows that the ordinarily skilled artisan would have been highly motivated to use routine experimentation to polymerize chemically distinct polyester "A" blocks and link them aliphatically, in order to produce the instantly claimed multiblock copolymer chain. Furthermore, Examples 8 and 10, respectively teach the use of larger weight polyester compounds, most notably PCL1250 and PCL4000. Therefore, in view of these combined teachings of Cohn, it would also have been within the purview of the skilled artisan to prepare polymerized "A" blocks comprising repetitive monomer units of ϵ -caprolactone, in order to achieve the instantly claimed, higher molecular weight embodiments of pre-polymer (B).

Cohn et al. do not expressly teach pre-polymer (B) (e.g. polycaprolactone) as being present between 30-50 wt% of the composition, as claimed by Applicant. Since the values of each parameter with respect to the claimed composition are adjustable, it follows that each is a result-

effective parameter that a person having ordinary skill in the art would routinely optimize.

Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill, in view of the teachings of Cohn, to prepare a multiblock copolymer composition comprising 30-50 wt% of polycaprolactone, particularly in view of ¶[0135] which teaches that an amount of the “A” blocks may comprise at least about 25-30% by weight of the ACA triblock copolymers. This teaching is interpreted as reading on weight percentages which are greater than 30 wt% and which include 50 wt%, though not expressly so. The teachings of PCL1250 and PCL4000 in Examples 8 and 10 supports the optimization of the weight of PCL and thus its overall compositional weight. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicant's invention.

RESPONSE TO ARGUMENTS

Applicants' arguments with regard to the rejection of claims 1, 3, 4, 9, 13, 14 and 31-37 under 35 USC 103(a) as being unpatentable over the teachings of Cohn et al. (US Pre-Grant Publication 2001/0009662) have been fully considered but they are not persuasive.

As an initial matter, it is not particularly clear to the Examiner where in the Remarks, the new rejection over Cohn '266, alone, is addressed. It appears that there are a few remarks made within the Declaration which are briefly directed to the Cohn reference. Absent an alternative showing, said remarks will be considered as Applicants' response and addressed below.

Applicants allege in their Declaration, submitted under 37 CFR 1.132, that the Cohn reference describes very specific preparations which have the structure of “-BA-Q-AB-” (¶13) and

“-ACA-Q-ACA-Q-” (§14). Applicants further allege that these polymers “are always controlled in their alteration” [*emphasis added*] (§15). Lastly, Applicants assert that Cohn is not random and is distinguishable from the instant invention because, for example, “a single multi-block copolymer of A of whatever composition or length is always followed by block C of whatever composition or length” and because Cohn (as well as Penco) is always 50:50 for A:B diblocks and 66:33 for A:C:A triblocks (§16) [*emphasis added*].

In response, the Examiner respectfully disagrees and maintains that there is nothing in the instant base claim which precludes the use of diblocks or triblocks from comprising the multiblock polymers. It is understood that Applicants’ invention is directed to a random, multiblock copolymer. However, contrary to Applicants’ assertions, the Cohn reference defines both the “A” and “B” blocks as being either monomeric or polymeric, thereby minimally suggesting randomness to the very nature of the diblock. This is further and necessarily applied to the “ACA” triblock embodiments. Furthermore, Cohn expressly teaches in ¶[0012] that the multiblocks may be polymerized through coupling or crosslinking of the diblocks. It is further taught and suggested in the discussion of “crosslinking” at ¶[0141], that the already randomly defined di- and tri-block copolymers may be bound to other diblocks, triblocks and other moieties of the invention. Lastly, concerning Applicants’ assertion pertaining to the order of the copolymer blocks, the Examiner maintains that an “A” block is not always or necessarily followed by either a “B” or “C” block, as evidenced by the forgoing discussion. It is possible, that an “AB” block may be followed by a “BA” block or an “ACA” block.

For these reasons, Applicants’ arguments are found unpersuasive. Said rejection is therefore **maintained**.

NEW REJECTIONS

In light of the forgoing withdrawn rejection, the following rejections have been newly added:

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-8, 10-12, 15-17 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Cohn '266, already made of record, with respect to claims 1, 13 and 14, in further combination with Tang et al. (USPN 5,066,772).

The limitations of claims 1, 13 and 14 are discussed above. As discussed above, Cohn teaches and suggests the limitations for the instantly claimed random, multiblock copolymer. Further evidence of this is provided in the teachings of Tang et al. which expressly defines random copolymer fabrication in terms of both the "A" and "B" block (col. 7, line 59 to col. 8, line 33). Of particular note is that the components of each block may comprise a single type of recurring monomeric unit or, alternatively, each may comprise multiple type of recurring monomeric unit, randomly distributed throughout the each block (col. 8, lines 10-15). Further discussed, with respect to the A's and B's is that they may be either the same or different, such that, for example, ABABA may be defined as MNOPQ, or ABA may be defined as MNQ, or ABA may be defined as MNOPQ (col. 8, lines 27-32).

Additionally, recited limitations to pre-polymer (A) include that it is prepared from diols, dicarboxylic acids and hydrocarboxylic acids (claim 5), that it comprises reaction products of either or both cyclic monomers (claims 6 and 7) and/or non-cyclic monomers (claims 6 and 8). Cohn teaches, for example, at ¶[0012] that the "A" block is prepared from the polymerization of such monomers as lactic, glycolic and/or hydroxybutyric acids (claims 5, 6 and 8) as well as such monomers as lactide, glycolide, ϵ -caprolactone, δ -valerolactone, trimethylene carbonate, *p*-dioxanone, and 1,4-dioxepan-2-one. The limitations are considered as being expressly taught in view of the "A" block definition provide by Cohn, in light of the evidence provided by Tang, as discussed above.

The limitation of claim 10 wherein the instantly claimed pre-polymer (A) is "prepared by" a ring-opening reaction, is considered by the Examiner as reading on the limitations of claim 1. Claim 12 recites the same limitation with respect to the pre-polymer (B) component. The "prepared by" limitations are interpreted in light of MPEP §2113 as reciting a product-by-process limitation, which while not rendering the claims improper, it does not serve to further limit the final, claimed composition.

The limitation of claim 11 recite that polyethylene glycol (PEG) is an initiator having a molecular weight ranging from 150-4,000. Cohn teaches, in an alternative embodiment that poly(ethylene glycol) varying in molecular weight from as low as 100 to hundreds of thousands or more may be used. A more preferred weight range is taught as ranging from about 550 to about 5,000 or more (see end of ¶[0012]).

The limitations of claims 15 and 16 are directed to the pre-polymer (B) component recited in claim 14 wherein poly-ε-caprolactone has a molecular weight of greater than 1,000 and that it represents 10-90 wt% of the composition. Cohn, while teaching and suggesting that "A" blocks may be comprised of polymerized ε-caprolactone, does not expressly teach a molecular weight for said polymer nor does it teach that it represents 10-90 wt% of the overall copolymer. However, such parameters with respect to the claimed composition are adjustable, and it follows that each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. As evidenced by Tang, for example, through use of selected monomer units and their arrangement in the polymer chain, different properties of the resulting randomly arranged polymer may result. Such properties include thermal history, pliability, hardness, softness, etc. (col.

8, lines 33-50). Thus, it would have been customary for an artisan of ordinary skill, to adjust the molecular weight and/or presence of a polymeric component such as poly-ε-caprolactone in order to affect changes to the hardness, softness and/or pliability parameters of the resulting polymeric composition, particularly in further view of Tang (col. 7, lines 10-35 and col. 9, lines 30-50), in order to achieve the desired composition. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicants' invention.

With regard to the intrinsic viscosity limitation recited in claim 17, which states that the composition of claim has "an intrinsic viscosity of at least 0.1 dL/g"; until some material differences in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward the polymer composition, which is instantly claimed.

Lastly, claim 27 is directed to an implant composition comprising the copolymer composition of claim 1. Paragraph [0094] of Cohn teaches that the practiced polymer compositions may be used to prevent adhesion between tissue and implants or devices which would occur after surgical procedures. This is interpreted by the Examiner as a teaching, if not a suggestion, that surgically implanted devices may have incorporated or associated with them the practiced polymeric compositions in order to prevent adhesion to the tissues. Further evidence of this interpretation is again provided by Tang which is expressly directed to medical devices which are fabricated, totally or in part, from copolymers of recurring units derived from monomers, such as those which are instantly claimed (Title, Abstract and above discussion).

As such, it would have been *prima facie* obvious for a person of ordinary skill in the art at the time of the invention to have arrived at the instantly claimed compositions. The ordinarily

skilled artisan would have been motivated to create the random multiblock copolymers connected PEG chain extenders for the reasons already discussed above. Namely, in view of the guidance provided by Cohn and further evidenced by Tang, it would be within the purview of the skilled artisan to produce different and randomly defined polymer blocks which are interconnected by PEG chain extenders. Tang provides additional evidence and motivation which supports the argument that segments of di- and/or triblock copolymers (i.e. "A" block) may be further sub-defined by different combinations of monomers in order to achieve the instantly claimed composition.

Thus, based on the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

All claims have been rejected; no claims are allowed.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/Carlos A. Azpuru/
Primary Examiner, Art Unit 1615